

REMARKS**Interview request**

Applicants respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative at (858) 720-7961. In compliance with Rule 133 (37 C.F.R. §1.133), a PTO 413A Applicant Initiated Interview Request Form is attached herein.

Status of the Claims*Pending claims*

Claims 14-19 and 21-24 are pending. Prior to Applicants' last response and amendment, filed 5/29/2007, claims 14-19 and 21-22 were pending. In Applicants' 5/29/2007 response, claims 14-19, 21 and 22 were amended and claims 23 and 24 were added. Based on the telephone conversation with the Examiner on 2/5/2008, Applicants have learned that the 5/29/2007 amendments have not been entered. Accordingly, those amendments are resubmitted herein, along with further amendments as explained below.

Amended claims

Claims 14, 15, 17, 18, 19 and 23 have been further amended to clarify the invention. Accordingly, upon entry of the amendments, claims 14-19 and 21-24 will be pending. Entry of the amendments and reconsideration in view of the following comments is respectfully requested.

With respect to all amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Amendments to the Specification

The Examiner states on page 2 of the Office Action mailed 11/30/2006 that the amendment to the specification filed November 7, 2006 has not been entered because the amendment does not comply with 37 C.F.R. § 1.121.

Therefore, the last amendments to the specification that *were* entered were those contained in Applicant's Response to Notice of Non-compliant Amendment mailed March 2, 2006 and Amendment in Response to Non-final Office Action, mailed November 18, 2005, as acknowledged by the Examiner on page 2 of the Office Action mailed May 12, 2006.

Thus, the amendments to paragraph [2] included on page 2 of this response are made to the specification as it appears after the November 18, 2005 and May 12, 2006 responses were entered.

Claim Amendments of 5/29/2007 Are Within the Elected Group IV

The Office alleges that the amendments filed with Applicants' last response of 5/29/2007 are not responsive to the previous Office action mailed 11/30/2006 because the amended claims are drawn to an invention that is related to but distinct from the originally elected Group IV, drawn to gene design. The Examiner further alleges that the two inventions are mutually exclusive, not obvious variants and have different modes of actions, functions and effects, and produce different results. Applicants respectfully traverse for reasons set forth in detail, below, and aver that the amended claims are completely within the scope of the elected Group IV.

Group IV, as set forth in the Restriction Requirement of September 27, 2002, is drawn to "gene design", including *inter alia* Group 702, subclass 20, and included e.g., the invention as set forth in then pending claims 14 to 17. Applicants respectfully aver that the claims as amended Applicants' last response of 5/29/2007 are also drawn to the elected "gene design" Group.

Related inventions are distinct if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and

wherein at least one invention is patentable (novel and nonobvious) over the other (though they may each be unpatentable over the prior art). MPEP § 802.01.II. The burden is on the examiner to provide an example to support the determination that the inventions are distinct. Under MPEP § 806.05(j), related inventions are distinct if:

- (A) the inventions as claimed do not overlap in scope, i.e., are mutually exclusive;
- (B) the inventions as claimed are not obvious variants; and
- (C) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect.

Applicants respectfully submit that the amended claimed methods of designing a polyketide synthase (PKS) gene capable of producing a desired polyketide are completely within the scope of the elected Group IV, and to explain and clarify this issue, present a claim chart wherein the relevant portions of original and amended claim 14 are summarized:

Original Claim 14	Amended Claim 14
Defining a string of alphanumeric symbols representing the structure of said polyketide.	Defining the structure of the desired polyketide by a first string of alphanumeric symbols, wherein each symbol in the first string represents a monomer unit of the polyketide.
Comparing said string to a database of strings of alphanumeric symbols representing polyketides producible by PKS genes.	Comparing the first string of alphanumeric symbols to a second string of alphanumeric symbols from a database, wherein the database comprises at least one second string of alphanumeric symbols representing a known polyketide, and wherein each alphanumeric symbol in the second string represents a monomer unit of the known polyketide and also represents a polyketide module of the polyketide synthase.
Identifying common elements in said string representing the structure of said desired polyketide with elements in said strings in said database.	Identifying a common alphanumeric symbol or continuous sequence of alphanumeric symbols in said first and second strings.
Generating... one or more new strings from elements identified in step (c) that have an exact match with said string representing the structure of said desired polyketide, wherein said new string defines a PKS gene capable of producing said desired polyketide.	Generating an alignment, wherein the alignment consists of a combination of common alphanumeric symbols identified from the database such that the sequence of alphanumeric symbols in the alignment matches the first string, and wherein the alignment represents the structure of a new PKS gene capable of producing the desired polyketide.

A. Defining the structure of a polyketide

The Office alleges that “defining the structure of the desired polyketide by a first string of alphanumeric symbols, wherein each symbol in the first string represents a monomer unit of the polyketide” is patentably distinct from “defining a string of alphanumeric symbols representing the structure of said polyketide” (emphasis added).

Applicants respectfully submit that the two clauses are semantically equivalent. In both cases, a string of alphanumeric symbols is used to characterize the structure of a desired polyketide. For illustrative embodiments of this step, the Examiner is referred to paragraphs [39] - [53], Example 2, and Figures 2 and 3 of the specification as filed, and to original claims 4 and 6. The only difference between the two formulations is the order of the terms “structure” and “string of alphanumeric symbols.” The original version of claim 14(a) recites a string of symbols representing structure, whereas the amended version recites structure defined by a string of symbols. According to the Merriam-Webster Online Dictionary, the terms “represent” and “define” are both synonymous with the verb “characterize” (see, e.g., <http://www.merriam-webster.com/thesaurus/characterize>; attached as **Exhibit A**). Thus, a person of ordinary skill in the art would easily recognize that the two versions of claim 14(a) are substantially identical in scope and therefore cannot be mutually exclusive.

B. Comparing the first and second strings

The Office further alleges that “comparing the first string of alphanumeric symbols to a second string of alphanumeric symbols from a database, wherein the database comprises at least one second string of alphanumeric symbols representing a known polyketide” is patentably distinct from “comparing said string to a database of strings of alphanumeric symbols representing polyketides producible by PKS genes” (emphasis added).

In the original claim 14(b), the target string of alphanumeric symbols representing the structure of the desired polyketide was compared to a database of strings representing polyketides producible by known PKS genes. The specification at paragraphs [55] - [60] teaches that the present invention provides, *inter alia*, a computer program that can read in polyketide library entries to an array or list of data structures, where each entry data structure contains all or a selected subset of the fields in each library record. It is obvious to a person skilled in the art that the database must contain one or more records to have any value to the user. The program then reads in a coded target polyketide string from a user and runs an alignment algorithm that compares the target string with the coded polyketide strings stored in the database. Moreover, paragraphs [61] - [64] of the specification teach that this comparison process is sequential, such that the target string is compared to individual library strings one at a time, until eventually all the library records have been exhausted. This is perfectly consistent with the language of amended claim 14(b), wherein the target string is compared to “a second string of alphanumeric symbols from a database, wherein the database comprises at least one second string of alphanumeric symbols representing a known polyketide.” Thus, the inventions claimed in the original and amended claim 14(b), if not identical, at least show a significant overlap in scope. Therefore, Applicants respectfully submit that these two inventions cannot be patentably distinct according to MPEP § 806.05(j).

C. Identifying a common symbol or sequence

The Office further alleges that “identifying a common alphanumeric symbol or continuous sequence of alphanumeric symbols in said first and second strings” is patentably distinct from “identifying common elements in said string representing the structure of said desired polyketide with elements in said strings in said database” (emphasis added).

The Merriam-Webster Online Dictionary defines the term “*element*” as “one of the parts that make up a whole” (<http://www.merriam-webster.com/thesaurus/element>; attached as **Exhibit B**). As discussed above, the strings representing polyketide structures of the present invention are composed of alphanumeric symbols, which by definition are “elements” of said strings. Thus, the smallest possible “element” of a string consists of a single alphanumeric symbol, whereas larger

“elements” consist of sequences of two or more symbols. The original version of claim 14(c) recites “identifying common elements in said string representing the structure of said desired polyketide with elements in said strings in said database.” Based on the teachings of the present specification and on the commonly accepted interpretation of the term “element,” a person skilled in the art would recognize that the original claim 14(c) refers to common alphanumeric symbols or symbol sequences between the target polyketide string and the strings stored in the database. Once again, this is perfectly consistent with the language of the amended claim 14(c), which refers to a common symbol or continuous sequence of symbols in the first and second strings. Accordingly, Applicants respectfully submit that, due to the extensive overlap in the scope of the original and amended claim 14(c), these claims cannot properly be characterized as distinct.

D. Generating an alignment representing a PKS gene

The Office finally alleges that “generating an alignment, wherein the alignment consists of a combination of common alphanumeric symbols identified from the database such that the sequence of alphanumeric symbols in the alignment matches the first string, and wherein the alignment represents the structure of a new PKS gene capable of producing the desired polyketide” is patentably distinct from “generating... one or more new strings from elements identified in step (c) that have an exact match with said string representing the structure of said desired polyketide, wherein said new string defines a PKS gene capable of producing said desired polyketide” (emphasis added).

Once again, Applicants respectfully submit that the original claim 14(d) and the amended claim 14(d) have substantially identical scope and simply represent two different ways of expressing the same idea. The original claim 14(d) recites: (1) one or more new strings, (2) composed of the common elements identified in step (c) (i.e., common symbols or symbol sequences, per discussion above), (3) that match exactly the target polyketide string, (4) such that the new string defines (i.e., represents, per discussion above) a PKS gene capable of producing the target polyketide. Consistent with that notion, the amended claim 14(d) recites: (1) an alignment (i.e., a new string, as explained in paragraphs [61] – [63] and Examples 3 and 4 of the specification), (2) that consists of a

combination of common alphanumeric symbols (i.e., common symbols or symbol sequences) identified from the polyketide string database [in step (c)], (3) that matches the target polyketide string, (4) such that the alignment represents (i.e., defines, per discussion above) the structure of a new PKS gene capable of producing the target polyketide. Thus, once the two method steps are broken down into basic elements, it becomes apparent that they overlap in scope to a great extent, thereby negating the Examiner's assertion that they are patentably distinct.

Based on the foregoing discussion, a person skilled in the art would appreciate that that the amended claims submitted with the response filed 5/29/2007 are drawn to the same invention as the originally elected Group IV, drawn to gene design. Accordingly, Applicants respectfully submit that these amendments be entered and the claims examined on the merits.

CONCLUSION

In view of the amendments and remarks in this response and Applicant's response of May 29, 2007, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. **300622005500**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

As noted above, Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this application. After the Examiner has reviewed the instant response and amendment, please telephone Applicants' representative at (858) 720-7961.


Dated: February 8, 2008

Respectfully submitted,

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EXHIBIT A



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Dictionary • Thesaurus Spanish/English Medical

characterize

One entry found.

characterize[verb]

Entry Word: **characterize**
Function: *verb*

Text:

1 to point out the chief quality or qualities of an individual or group <how would you *characterize* the mission of this environmental organization?>
Synonyms define, depict, describe, portray, represent
Related Words categorize, classify, pigeonhole, type; identify, indicate, name, specify; distinguish, individualize, mark, particularize, stamp

2 to be an important feature of <an unsightly rash *characterizes* chicken pox>
Synonyms distinguish, mark
Related Words differentiate; customize, individualize, particularize

For More Information on "characterize" go to Britannica.com
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element

One entry found.

element[noun]

Entry Word: **element**

Function: *noun*

Text:

1 one of the parts that make up a whole <a free press is an essential *element* of a democracy>

Synonyms component, constituent, factor, ingredient, member

Related Words detail, item, particular, point; aspect, characteristic, facet, feature, trait; division, fragment, particle, piece, portion, section, sector, segment

Near Antonyms aggregate, composite, compound, sum, total, totality

Antonyms whole

2

elements *plural*

general or basic truths on which other truths or theories can be based <the *elements* of mathematics can be traced back to Euclid> — see **PRINCIPLES 1**

Physician-reviewed articles on **element** on Healthline.

1. Diffusion and Adoption of Innovations

Overall, innovations that are perceived by individuals as...

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